UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 26, 2016

MEMORANDUM

Subject: ADDENDUM to Efficacy Review for EPA Reg. No. 85134-1, Anolite;
DP Barcode: 432778
E-Sub #: 10577

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller PM 32/Wanda Henson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Envirocleanse LLC
12621 W. Airport Rd.
Sugar Land, TX 77478

FORMULATION FROM LABEL:

Active Ingredient	% by wt.
Hypochlorous acid	0.025%
Other ingredients	99.975%
Total	100.000%

I BACKGROUND

The product, Anolite (EPA Reg. No. 85134-1), is an EPA-approved food contact surface sanitizer, disinfectant (bactericide), and deodorizer/cleaner for use on pre-cleaned, hard, non-porous surfaces in residential and commercial environments. With this application the registrant is seeking to add claims of effectiveness against Norovirus (data provided on acceptable surrogates, Murine Norovirus and Feline Calicivirus). The registrant is seeking to expand some label uses and to add claims consistent with the registrant's own efficacy data and other registered hypochlorous acid products. Additional uses added include general cleaning uses, deodorizing uses, veterinary clinics and agricultural uses. All added uses rely upon previously submitted data by the registrant or are considered non-public health uses. In addition to adding approved hypochlorous acid uses and expanded claims, the registrant is replacing the primary brand name of the product, changing it from "Anolite" to "Envirocleanse500." Studies were conducted at MicroBioTest, located at 105 Carpenter Drive, in Sterling, VA 20164. This data package contained a letter from the applicant to EPA (dated March 11, 2016), two studies (MRID 49837901 and 49837902), Statements of No Data Confidentiality Claims for all studies, and the proposed draft label (3/9/16).

With this addendum, changes to the original Data Evaluation Record (dated July 18, 2016) are being made based on additional information submitted by the registrant regarding the test material active ingredient concentration for MRIDs 49837901 and 49837902.

II USE DIRECTIONS

The proposed label contains the following use directions:

Anolite is a disinfectant for use on hard non-porous inanimate surfaces. Anolite is an oxidized, pH-neutral water based solution that is ready-to-use. When used according to the directions for use, this product disinfects hard, non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, enamel and glazed tile.

Disinfection of Hard, Non-porous Surfaces:
Anolite can be used to disinfect hard, non-porous surfaces including: countertops, sinks, toilets, tables, chairs, appliances (exterior surfaces), desks, beds (rails, frames, headboards, footboards), floors, computer keyboards, door knobs and similar surfaces. To disinfect, apply Anolite to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. Remove gross filth from surfaces before applying this product. Small nonporous objects can also be soaked in Anolite without dilution. Allow objects to soak for 10 minutes.

Sanitization of Hard Non-porous Food Contact Surfaces
Anolite is an effective sanitizer against gram positive and gram negative bacteria (vegetative forms) such as *Staphylococcus aureus* and *Escherichia coli.* For use in schools, colleges, industrial and commercial facilities, restaurants, office buildings, recreational facilities, retail and wholesale establishments, food processing facilities, homes, apartments, and condos. Anolite is a sanitizer for use on pre-cleaned non- porous, food contact surfaces including food preparation and storage areas, dishes, glassware, silverware, eating and cooking utensils, plastic and nonporous cutting boards and chopping blocks, other kitchen products used in food preparation, other utensils, coolers, tables, counter tops, sinks, shelves, racks, carts, refrigerators, coolers, glazed tile, refrigerators, microwaves, ovens and stove tops, sinks, appliances, conveyor belts.

As well, Anolite can be used in direct food application at dose not to exceed 200 ppm FAC of Anolite. For direct use on food contact surfaces, please dilute Anolite 1:1 with tap water, which provides active Anolite (this product) at 169 ppm FAC. Prior to application, remove gross food particles and soil by a pre-flush or pre-scrape and when necessary, presoak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner, followed by a potable water rinse before applications of the sanitizing solution. To sanitize, apply Anolite to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 60 seconds. Allow treated surface to air dry. Remove gross filth from surfaces before applying this product.

III PROPOSED CHANGES TO CONCLUSIONS

The following conclusions were made as part of the DER dated July 18, 2016.

1. *The submitted efficacy data **do not support** the product as a disinfectant against the following viruses on hard, non-porous surfaces with a 5% organic soil load for a 10-minute contact time at room temperature (20°C):*

Feline Calicivirus (ATCC VR-782)	*498379-01*
Murine Norovirus (Yale University)	*498379-02*

According to the active ingredient concentration analysis on the last page of each report, these studies were performed with a hypochlorous acid concentration in excess of the nominal concentration of the product. These studies should have been performed with an active ingredient concentration at the product's lower certified limit.

The following change to the 7/18/16 review is being made based on additional information submitted by the registrant regarding the test material active ingredient concentration:

1. The submitted efficacy data **do support** the product as a disinfectant against the following viruses on hard, non-porous surfaces with a 5% organic soil load for a 10-minute contact time at room temperature (20°C):

Feline Calicivirus (ATCC VR-782)	498379-01
Murine Norovirus (Yale University)	498379-02

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

RECOMMENDATIONS

1. The label claims that the product is a disinfectant against the following virus on hard, non-porous surfaces for a 10-minute contact time.

   Norovirus (Feline Calicivirus and Murine Norovirus as surrogates)

This claim is <u>acceptable</u>.